



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Zheng J. Li, et al.

Examiner: BERKO,
RETFORD O.

APPLICATION NO.: 10/652,655

Group Art Unit: 1618

FILING DATE: AUGUST 28, 2003

TITLE: CRYSTAL FORMS OF AZITHROMYCIN

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER RULE §131

I, Joseph E. Mertz, declare that:

1. I received my Bachelor of Science degree in Pharmacy in December 1994 from the College of Pharmacy and Health Sciences at Drake University in Des Moines, Iowa.
2. Since December 1994, I have been working at Pfizer, Inc. in Groton-CT on liquid formulations. I have also worked on determining the physical and chemical properties of new molecular entities (NME's) as it pertains to oral liquid and parenteral drug delivery.
3. Prior to May 8, 1998, I participated in the conception and reduction to practice of substantially pure Form F azithromycin claimed in the present application (see the X-RAY CRYSTALLOGRAPHY and Single Crystal X-Ray Crystallographic Analysis which are dated before May 8, 1998 and are attached herein as Exhibit 1). Exhibit 1 is redacted as to the dates of the documents which all occurred before May 8, 1998.
4. Exhibit 1 describes the crystal structure of a crystalline azithromycin compound having an azithromycin:water:ethanol ratio of about 1:1:0.5. I believe that the crystalline azithromycin is substantially pure Form F azithromycin. Such substantially pure Form F azithromycin was made and characterized prior to May 8, 1998.

5. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



JOSEPH E. MERTZ

07 JUL 2005

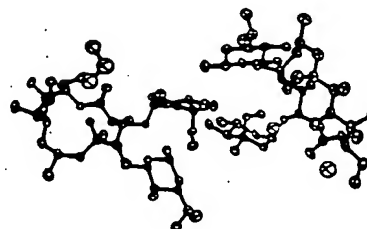
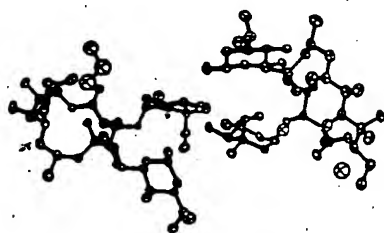
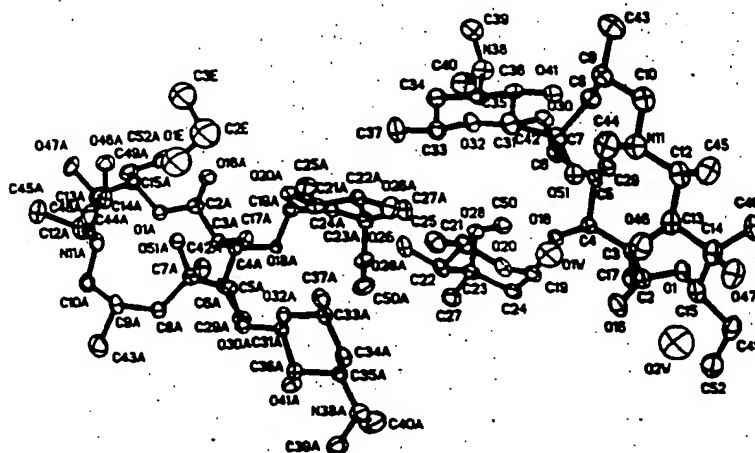
DATE

EXHIBIT 1

X-RAY CRYSTALLOGRAPHY

JON BORDNER

DEBRA DECOSTA





A. Crystal Parameters

formula	$C_{38}H_{72}N_2O_{12} \cdot 2H_2O +$ $C_{38}H_{72}N_2O_{12} \cdot C_2H_5OH (1580.4)$
crystallization medium	apricot oil and ethanol
crystal size, mm	0.14 X 0.20 X 0.24
cell dimensions	$a = 16.281(2) \text{ \AA}$ $b = 16.293(1) \text{ \AA}$ $c = 18.490(3) \text{ \AA}$ $\alpha = 90.0^\circ$ $\beta = 109.33(1)^\circ$ $\gamma = 90.0^\circ$ $V = 4628(1) \text{ \AA}^3$
space group	$P2_1$
molecules/unit cell	2
density calcd, g/cm ³	1.134
linear absorption factor, mm ⁻¹	0.692

B. Refinement Parameters

number of reflections	4975
nonzero reflections ($I > 3.0\sigma$)	4350
R-index ^a	6.88%
GOF ^b	1.11
secondary extinction factor ^c , χ	NONE

^a $R\text{-index} = \sum |F_o| - |F_c| / \sum |F_o|$

^b $GOF = [\sum w(F_o^2 - F_c^2)^2 / (m-s)]^{1/2}$

where $w = [\sigma^2(F) + |g|F^2]^{-1}$ $g = .0073$

^c $F^* = F[1 + 0.002\chi F^2 / \sin(2\Theta)]^{-1/4}$



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,254	08/27/2003	Zheng J. Li	PC11724C	7453
28523	7590	07/12/2004	EXAMINER	
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340			PESELEV, ELLI	
			ART UNIT	PAPER NUMBER
			1623	
DATE MAILED: 07/12/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.



Notice of Abandonment

Application No.	Applicant(s)	
10/650,254	LI ET AL.	
Examiner	Art Unit	
Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on December 3, 2003.
 - (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
 - (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
 - (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
 - (d) ☐ No reply has been received.
2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
 - (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
 - (b) ☐ The submitted fee of \$_____ is insufficient. A balance of \$_____ is due.
The issue fee required by 37 CFR 1.18 is \$_____. The publication fee, if required by 37 CFR 1.18(d), is \$_____.
 - (c) ☐ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
 - (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
 - (b) ☐ No corrected drawings have been received.
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. ☐ The reason(s) below:

elli peselev
ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.